IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| ROCHE DIAGNOSTICS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>MESO SCALE DIAGNOSTICS, LLC.,<br><br>Defendant. | ) | C.A. No. 17-189 (LPS) (CJB)<br><br>PUBLIC VERSION<br>FILED ON: May 22, 2019 |
| MESO SCALE DIAGNOSTICS, LLC.,<br><br>Counterclaim Plaintiff,<br><br>v.<br><br>ROCHE DIAGNOSTICS CORPORATION and BIOVERIS CORPORATION,<br><br>Counterclaim Defendants. | ) | |

**ROCHE DIAGNOSTICS CORPORATION AND BIOVERIS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND DAUBERT MOTIONS**

Joel Friedlander (Del. Bar No. 3163)
Christopher Foulds (Del. Bar No. 5169)
FRIEDLANDER & GORRIS P.A.
1201 N. Market Street, Suite 2200
Wilmington, DE 19801
(302) 573-3500
jfriedlander@friedlandergorris.com
cfoulds@friedlandergorris.com

*Attorneys for Roche Diagnostics Corporation and BioVeris Corporation*

OF COUNSEL:

James T. McKeown (admitted PHV)
Jeffrey N. Costakos (admitted PHV)
Eric L. Maassen (admitted PHV)
Kimberly K. Dodd (admitted PHV)
Rachel M. Blise (admitted PHV)
Philip C. Babler (admitted PHV)
FOLEY & LARDNER LLP
777 East Wisconsin Avenue
Milwaukee, WI 53202
(414) 271-2400

Dated: May 15, 2019

**TABLE OF CONTENTS**

**Page No.**

## TABLE OF CITATIONS

**Federal Cases** **Page(s)**

**State Cases**

**Federal Statutes**



**State Statutes**



**Other Authorities**

## INTRODUCTION

Defendant/Counterclaim Plaintiff Meso Scale Diagnostics, LLC. ("Meso"), after losing its contract claims in the Delaware Court of Chancery, seeks remedies under patent law against Plaintiff/Counterclaim Defendant Roche Diagnostics Corporation ("Roche") and Counterclaim Defendant BioVeris Corporation ("BioVeris"). Roche and its affiliates obtained rights to practice its electrochemiluminescence ("ECL") detection technology in the accused products through their acquisition of three companies: (1) Boehringer Mannheim GmbH (in 1998), which had obtained a license in 1992 from IGEN, Inc., the original assignee of most of the patents in suit;[1] (2) IGEN (in 2003), upon termination of the *IGEN v. Boehringer Mannheim/Roche* litigation, at which time Roche obtained what is described below as the "2003 License" from IGEN; and (3) BioVeris (in 2007), IGEN's successor to the relevant patent rights and Roche's affiliate. All told, Roche's affiliates paid over $2 billion to acquire ownership of patents and license rights to practice the patented ECL technology.

As discussed in the Phase I summary judgment briefs, Meso claims exclusive rights to certain patents under a 1995 license agreement (and 2001 amendment) between Meso and IGEN. BioVeris, now a Roche affiliate, owns those patents, and Meso admits that Meso's consent to the 2003 License between IGEN and Roche bars any challenge to sales of products sold within the Field in the 2003 License. Yet, Meso contends that its license rights prevent Roche from selling products outside that Field. Meso's claims turn, in part, on whether Roche's immunoassay customers use some of the accused Roche products *only* outside the 2003 License Field (referred

[1] Boehringer Mannheim was in litigation with IGEN over the ECL technology when Roche acquired it.

to as "single-use" out-of-Field customers) or both for permitted, in-Field diagnostic uses and also out of the Field (so-called "dual-use" customers).

Roche brings this motion for partial summary judgment on the grounds that:

(1) Meso is bound by its consent and the judgment in the prior case between these parties and cannot bring infringement claims based on Roche's non-deliberate sales to "dual-use" customers.

(2) Meso has no evidence upon which a jury could find that Roche is liable for indirect infringement as to dual-use customers.

(3) Roche's reagent packs are not "kits" under Claim 82 of the '939 Patent and Claims 1, 26, 28, and 29 of the '485 Patent, as those claims have been construed in this Court's *Markman* decision.

(4) Several of Roche's reagent packs do not infringe claim 10 in the '607 Patent, as that claim has been construed in this Court's *Markman* decision.

(5) Roche's instruments contain reusable, platinum electrodes and, therefore, do not infringe on Meso's rights under the Meso Joint Venture Agreement ("JVA") and the IGEN/Meso License Agreement to exclusive use of "disposable electrodes."

As explained below, summary judgment on these factually undisputed claims simplifies the case for trial, reduces the number of patents at issue, and focuses the trial on the issues where material facts are genuinely disputed: The scope of Meso's claimed license rights and Roche's alleged out-of-Field sales to "single-use" customers.

Roche also moves to exclude or limit the testimony of two witnesses from whom Meso intends to offer expert testimony. Mr. Quentin Mimms, Meso's damage expert, relies on an inappropriate date for the hypothetical negotiation, fails to apportion value to other patents, and applies a "hold up" rate of [redacted] rather than a reasonable royalty analysis. Dr. James Wilbur, the General Manager of Meso, apparently intends to offer opinions for which he lacks proper expertise and foundation, and which fall outside the scope of his percipient knowledge.

## NATURE AND STAGE OF PROCEEDINGS

Roche filed a Phase 1 dispositive motion on August 22, 2018. (D.I. 98.) The Court denied Roche's motion on March 21, 2019. (D.I. 154.) Fact discovery has closed (D.I. 25), subject to stipulations by the parties concerning certain fact discovery issues. Expert discovery was scheduled to be completed on May 3, 2019 (D.I. 146), but the parties agreed to depose certain experts later in May to accommodate the schedules of counsel and the experts. Phase II dispositive motions on infringement and damages and *Daubert* motions are due May 15, 2019. (*Id.*) Trial is scheduled to begin on November 12, 2019. (D.I. 25.)

## SUMMARY OF ARGUMENT

(1) Meso is bound by its consent to the 2003 License and cannot, by virtue of that consent, and by virtue of issue preclusion from the Delaware Court of Chancery decision, bring infringement claims based on Roche's non-deliberate sales to "dual-use" customers.

(2) Meso has no evidence that Roche is liable for indirect infringement, either contributory infringement or induced infringement, as to dual-use customers. No evidence shows that Roche has engaged in *active* inducement to infringe. Roche's products have a substantial non-infringing use, namely "in-Field" use.

(3) Roche's reagent packs are not "kits" under Claim 82 of the '939 Patent and Claims 1, 26, 28, and 29 of the '485 Patent, as those claims have been construed in this Court's *Markman* decision. The reagent packs do not include ProCell, a necessary component of any "kit" under these patent claims.

(4) Several of Roche's reagent packs do not infringe Claim 10 in the '607 Patent, as that claim has been construed in this Court's *Markman* decision.

(5) Roche's instruments contain reusable, platinum electrodes and, therefore, do not infringe license rights that Meso has to the use of "disposable electrodes."

(6) Mr. Mimms' [redacted] royalty model is inappropriate because it uses the wrong time for the negotiation of a hypothetical royalty, uses a "hold up" approach, and fails to apportion value to other patents and technology.

(7) Dr. Wilbur, identified as a Rule 26(a)(2)(C) witness, cannot offer opinions beyond his percipient knowledge and expertise.

## FACTS[2]

### A. The Accused Roche Products

ECL is the detection technology employed by Roche's immunoassay analyzers (D.I. 1 at ¶ 10 & D.I. 42 at Am. Answer ¶ 10), large automated medical diagnostic systems designed to test human blood and serum. Roche's accused immunoassay products are found in reference labs, hospitals, and other labs, where medical providers use them to diagnose patients with a range of health issues from heart attacks to thyroid issues to certain infectious diseases. (Ex. 56 at 242:16-243:6; *see generally* Ex. 54.) Immunoassay analyzers use antibodies to detect and measure the presence of an analyte in the patient sample. (D.I. 42 at Am. Counterclaim ¶ 69 & D.I. 48 at ¶ 69.) Roche's instruments/assays use the patented ECL technology as the detection mechanism. (D.I. 42 at Am. Counterclaim ¶ 20 & D.I. 48 at ¶ 20.) Roche licensed the ECL technology from IGEN and its successor BioVeris. (D.I. 1 at ¶¶ 12, 13, 15 & D.I. 42 at Am. Answer ¶¶ 12, 13, 15.)

Virtually all of Roche's immunoassay instruments and its assays (or tests) are accused products. Roche's immunoassay analyzers/instruments bear the brand names Elecsys 2010, Elecsys e 170, cobas e 411, cobas e 601, cobas e 602, and cobas e 801. (Ex. 53 at A-01646.) The instruments draw certain immunoassay reagents from a reagent pack[3] to conduct the actual assay. (*See generally* Roche Tutorial.) Some of the 10 patents in suit cover only instruments, others cover only reagents, still others are method patents for methods performed only by

---

[2] Roche's Motion for Summary Judgment on Track 1 (D.I. 98) provided the Court with a detailed factual background regarding Roche, Meso, and the parties' extensive litigation history. Roche provides the following additional facts and evidence in support of this Motion. All citations to "A-___" are to page numbers in the Appendix.

[3] Roche's reagent packs are containers that hold certain of the reagents for the immunoassay reactions. They do not include Roche's Procell product.

Roche's customers and not by Roche. Meso accuses essentially Roche's entire immunoassay portfolio in the United States, both instruments and reagents. (*See* Ex. 53.)

Roche's immunoassay products, instruments, and reagents are designed, and FDA approved, to be used to make medical decisions about human patients. These uses are sometimes called in-vitro diagnostics (IVD) testing. (*See* Ex. 56 at 152:4-11, 196:6-20.) Roche's ECL instruments are particularly suited for the IVD market because of (among other things) their automation, random access capability (*i.e.*, the ability to switch from performing one assay on the first sample to a different assay on the next sample), and their FDA approval. (*E.g.*, Ex. 50 at A-01625.) Most of Roche's immunoassay customers are hospitals, integrated health networks, and reference laboratories (Ex. 56 at 242:16-243:6), and Meso concedes that the vast majority of the immunoassay tests that Roche sells are used to aid medical decisions. (*E.g.*, Ex. 70 at ¶¶ 16-30.) The patents in suit relate only to the electrochemical reaction occurring in the flow cell of the instruments; the patents in suit do not implicate the robotics, automation, software, user interface, or many other features of the instruments that ultimately add value and drive sales.[4]

**B. The ECL Patents in Suit**

Ten BioVeris ECL patents are in suit, including both product and method patents. The following table summarizes Meso's position on infringement:

[4] Ex. 54 at A-01654; Ex. 61 at A-01837-A-01854; Ex. 2 (U.S. Patent Nos 5,466,416); Ex. 5 (5,714,089); Ex. 6 (5,846,485); Ex. 7 (5,935,779); Ex. 8 (5,962,218); Ex. 10 (6,078,782); Ex. 12 (6,165,729); Ex. 18 (6,271,041); Ex. 24 (6,316,607); and Ex. 33 (6,808,939). See generally Ex. 50.

**Infringing Products According to Meso**[5]

| Patent | Claim Type | Expiration Date | Accused Products |
|---|---|---|---|
| **'416** | Product | 5/14/2013 | [redacted] |
| **'089** | Product | 2/3/2015 | |
| **'485** | Product | 12/8/2015 | |
| **'779** | Method | 8/10/2016 | |
| **'218** | Method | 8/10/2016 | |
| **'782** | Method | 8/10/2016 | |
| **'729** | Method | 12/26/2017 | |
| **'041** | Method | 12/26/2017 | |
| **'607** | Product & Method | 11/13/2018 | [6] |
| **'939** | Product | 6/29/2021 | |

[5] Ex. 54 at A-01654; Ex. 2 (U.S. Patent Nos 5,466,416); Ex. 5 (5,714,089); Ex. 6 (5,846,485); Ex. 7 (5,935,779); Ex. 8 (5,962,218); Ex. 10 (6,078,782); Ex. 12 (6,165,729); Ex. 18 (6,271,041); Ex. 24 (6,316,607); and Ex. 33 (6,808,939).

[6] [redacted] (Ex. 54 at Ex. I, A-01704.) [redacted] (Ex. 63 at A-01971.)

Roche's affiliate BioVeris owns each of the patents and Roche agrees that a number of the accused products are or were covered by one or more patent under which Meso claims certain limited license rights. Roche disputes that Meso has any license rights that limit Roche's ability to practice the patents as it now practices them.[7] But even if Meso were right about the scope of its rights, the undisputed evidence shows that portions of Meso's claims should be dismissed. Particularly relevant here is that—with the exception of an installation and maintenance step—Roche does not conduct or control instruments that perform the steps of the method patents and therefore does not perform any of the methods covered by the method patents; they are performed solely by customers. (Ex. 74 at ¶ 4.) For product *sales* the patents expire as follows:

- **Instrument** sales through **May 14, 2013**
- **Reagent** sales for most immunoassay reagent packs through **February 3, 2015**
- **"Kit"** sales for reagent packs through **December 8, 2015**[8]
- **Reagent** sales on **two small subsets** of reagent packs, covered by the '607 and the '939 patents, through **November 13, 2018** and **June 29, 2021**, respectively.

### C. Roche and Meso's Respective ECL Patent/License Rights

#### 1. The 1992 Boehringer Mannheim License

[7] Roche also disputes the extent to which its products are covered by the patents. (*See* Exhibit 61.)

[8] As discussed below, the Court should grant summary judgment to Roche on the "kit" issue consistent with its *Markman* ruling. *Infra*, Argument Part II.

In 1992, IGEN licensed its ECL technology to Boehringer Mannheim ("BMG") for use in certain market fields. (Ex. 1.) A Roche affiliate later purchased BMG and the ECL development and commercialization efforts continued under Roche. (Ex. 59 at 37:18-20, 77:3-25.)

**2. The Meso Joint Venture**

In 1995, three years after the IGEN-BMG license was signed, IGEN and Meso Scale Technologies, LLC. ("MST") (a company owned by Jacob Wohlstadter ("Wohlstadter"), the son of IGEN's then-CEO Sam Wohlstadter) created the Meso Scale Diagnostics, LLC. ("Meso") joint venture to explore using Wohlstadter's technologies with IGEN's ECL technology. (Ex. 17 at 199:12-199:18; Ex. 16 at ¶ 3; Ex. 21 at A-00770.) Under the joint venture, both IGEN and MST licensed technology to Meso. (Ex. 3; Ex. 4.) Meso's commercial products use multi-array technology and employ disposable electrodes. (Ex. 46 at 263:19-264:9; Ex. 27 at A-01054-56.)

**3. Roche's 2003 License and the Acquisition of BioVeris**

**a. *IGEN v. Boehringer Mannheim/Roche* Litigation**

In 1997, IGEN sued Boehringer Mannheim in federal court in Maryland alleging that BMG had breached the 1992 License.[9] On July 9, 2003, the Fourth Circuit affirmed a jury finding that Roche had materially breached the 1992 License, giving IGEN the right to terminate that license. *See generally IGEN Int'l, Inc. v. Roche Diagnostics GmbH*, 335 F.3d 303 (4th Cir. 2003). [redacted] (Ex. 28), IGEN and Roche finalized the 2003 License to give Roche a broad license to use the IGEN ECL technology, including all of the Asserted Patents, for all human patient diagnostic uses. *Meso Scale Diagnostics, LLC. v.*

[9] During the course of the litigation, Roche's affiliate acquired BMG and assumed the defense.

*Roche Diagnostics GmbH*, 2014 WL 2919333, at *8-10 (Del Ch. 2014). In the transaction, all of IGEN's ECL technology was transferred to a new entity (i.e., BioVeris). (*Id.*)

Like the earlier 1992 license, the 2003 License allowed Roche to develop, make, and sell defined "Products" in a defined "Field." Specifically, through the 2003 License, Roche obtained the right to use its single-cell, platinum electrode ECL technology in the Field of human in vitro diagnostics, subject to certain out-of-Field exclusions (life sciences, patient self-testing, drug discovery, and also veterinary, food, water, and environmental testing). (Ex. 30 at §§ 1.4, 1.7, 2.1.) The 2003 License also granted Roche a license for evaluation of Products or for regulatory approval when Roche derives no revenue from those uses. (*Id.* § 2.7.)

IGEN obtained Meso's consent to the 2003 License and assurances that, whatever rights Meso had, these rights would not interfere with Roche's ability to sell products under the terms of the 2003 License. (Ex. 30 at A-01153.) Meso executed a series of agreements, including a "Consent" to the 2003 License whereby Meso "consent[ed] to and join[ed] in the licenses granted by IGEN." (*Id.*)[10]

IGEN and Roche understood that some out-of-Field sales were unavoidable. They, therefore, agreed in § 2.5 of the 2003 License: 1) that IGEN (later BioVeris) had no right to terminate the 2003 License for out-of-Field sales; and 2) that the "exclusive remedy" for any such sales shall be the payment "to IGEN" of "65% of all undisputed revenues earned through out-of-Field sales" and Roche could "continue to sell Licensed Products for out-of-Field uses" until IGEN notified Roche in writing that it was "prohibited from making any further such sales." (Ex. 30 at § 2.5(b).) This 65% payment, intended to be a profit disgorgement, was to be

[10] The Delaware Court of Chancery would later conclude that Meso was not a party to the 2003 License; the Consent, nevertheless, prevents Meso from claiming damages related to Roche's sales of products covered by that license.

in effect until the last patent in the IGEN patent portfolio expired *anywhere* in the world regardless of whether the products remained covered by unexpired patents. (Ex. 30 at § 1.15; Ex. 48 at 1052.) Under the provisions of the 2003 License, as long as any single one of the 100+ patents had not expired, Roche needed to pay IGEN (later BioVeris) 65% of revenues for sales out-of-Field even if all the patents in the country where the sale occurred had long expired. (Ex. 30 at §§ 1.15, 2.5.) BioVeris also had the right, at its election, to order Roche not to make future sales of products that were being used out-of-Field. (*Id.* at § 2.5(b).)

**4. Post-2003 Disputes Over Out-of-Field Sales**

Almost all of Roche's sales now—as has been true at all times since 2003—are made to customers who use Roche's products to diagnose and treat patients—*i.e.*, indisputably within the 2003 License Field. (Ex. 30 at § 1.7; *e.g.*, Ex. 56 at 242:16-243:6.) But Roche made some sales both to dual-use customers and to single-use out-of-Field customers beginning very shortly after the 2003 transaction. After BioVeris challenged some sales, Roche paid BioVeris 65% of the revenues Roche received for sales made out-of-Field to single-use customers in 2004. (Ex. 34 ([redacted]); Ex. 35 (press release acknowledging payment).)

[redacted] (*E.g.*, Ex. 44 at A-01339; Ex. 37.)

[redacted] (Ex. 44 at A-01339.)

[redacted] (Ex. 44 at A-01344.) [redacted]

[redacted] (*See* Ex. 44 at A-01344, A-0471.)

**5. Roche's Acquisition of BioVeris in 2007.**

Rather than continue the approach of an annual Field Monitor exercise, BioVeris and a Roche affiliate ultimately decided to enter discussions for the purchase of BioVeris. In April 2007, Roche's affiliate agreed to purchase BioVeris for approximately $600 million, thereby obtaining controlling ownership of the patented technology and BioVeris's ECL patents. (Ex. 38.) In connection with that acquisition, [redacted] (*See* Ex. 39; Ex. 60 at 52:3-54:2, 109:1-8, 129:23-130:13; Ex. 58 at 249:21-250:17.)

**D. Meso Unsuccessfully Sues Roche to Enforce the 2003 Field Restrictions.**

Meso filed suit in the Delaware Court of Chancery in 2010. (D.I. 42 at Am. Answer ¶ 22.) Meso alleged that its consent to the 2003 transaction prevented Roche from acquiring BioVeris in 2007 and that Meso was a party to the 2003 License with a right to enforce its provisions. (D.I. 42 at Am. Answer ¶¶ 23 & 26); *Meso v. Roche*, 62 A.3d 62, 64-65 (Del. Ch. 2013). Vice Chancellor Parsons granted summary judgment for Roche on Meso's first claim. (Ex. 47.) After a one-week trial on Meso's remaining claim, the court held that Meso had consented to the 2003 License but was neither a party to nor a third party beneficiary of it, and that only BioVeris could enforce that agreement as to sales made by Roche outside the Field defined in the 2003 License. *Meso Scale Diagnostics, LLC. v. Roche Diagnostics GmbH*, 2014 WL 2919333, at *29, 13 n.110 (Del Ch. 2014).

The Vice Chancellor made the following observation:

> That does not mean, however, that Roche had free rein to use the Licensed ECL Technology as it saw fit. There is no evidence that, in connection with the 2003 License Agreement or otherwise, Meso ever consented to or "joined in" any authorization for Roche to operate outside of the Field, regardless of whether Roche had another license to do so. Therefore, to the extent Roche may have chosen to operate deliberately outside of the Field, it ran the risk that it may be infringing on Meso's intellectual property rights by practicing Meso's ECL technology without having either Meso's consent or an effective license to do so. Meso conceivably may have viable infringement or other claims against Roche for its actions since 2007, when it allegedly began operating deliberately outside of the Field. The question of whether Roche infringed on Meso's ECL-related intellectual property rights, however, is distinct from, and has no bearing on, the breach of contract claim that Meso pursued at trial in this litigation.

*Id.* at *28.

## ARGUMENT

Summary judgment is appropriate when there exist no issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Here partial summary judgment is appropriate based on Meso's consent to the 2003 License. That consent, and the decision construing it, preclude Meso's claims for damages relating to Roche's "dual-use" customers. Meso also has insufficient evidence to prove contributory infringement or inducement, and certain accused products fall outside the technologies specified in the patent claims and Meso's claimed license rights. Finally, the testimony of Mr. Quentin Mimms and Dr. James Wilbur should be excluded or limited under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

### I. MESO'S CLAIMS RELATING TO DUAL-USE CUSTOMERS SHOULD BE DISMISSED.

Meso recognizes, as it must, that it has no infringement claim relating to sales by Roche of products that customers use within the Field of the 2003 License. (*See, e.g.*, D.I. 42 at Am. Counterclaim ¶¶ 20, 25, 27, 28 (asserting infringement against only uses of ECL technology

outside of the "Roche Licensed Field").) Meso cannot pursue any claims relating to Roche's "dual-use" customers, even as to those customers' uses outside of the 2003 License Field.

First, as the Delaware Court of Chancery held, Meso's consent to the 2003 License limits its potential patent infringement claims to, at most, *deliberate* out-of-Field sales. Therefore, all claims related to dual-use customers should be dismissed.

Second, Meso cannot prevail on its contributory infringement claim because there exist permissible uses of the accused products, and Meso cannot prove that Roche induced its customers to use the accused products outside the Field. Absent claims of indirect infringement, Meso cannot prevail against Roche under any of the method patents because the patented methods are run by Roche's customers. Summary judgment on these issues would eliminate liability for any damages after May 14, 2013 for instruments, after December 8, 2015 for any reagent packs considered kits, and after February 3, 2015 for most remaining reagent packs.

The Court should grant summary judgment on Counts 3, 4, 5, 6, 7, 8, 9 of the Counterclaim as to the indirect infringement claims and summary judgment on all counts of the Counterclaim as to dual-use customers on the ground that Meso's claims are barred by Meso's 2003 Consent and issue preclusion.

### A. Absent Proof of Sales Deliberately Made Out-of-Field, Meso's Claims Relating to Dual-Use Customers Are Barred by Meso's 2003 Consent and by Issue Preclusion.

Meso does not dispute its consent to the 2003 License (D.I. 42 at Am. Answer ¶ 14), and it implicitly acknowledges that its consent to the 2003 License circumscribes its claims (D.I. 42 at Am. Counterclaim ¶¶ 20, 25, 27, 28.) But Meso's consent to the 2003 License limits Meso's purported patent claims far more than Meso admits. Roche continues to dispute that Meso has *any* rights that limit Roche's sales of the accused products. But in any event the consent to the 2003 License and the decision construing it set a ceiling on Roche's potential liability even if

Meso should prevail. As explained above, the 2003 License permitted Roche to sell to customers who use Roche's products for in-Field use—*i.e.*, for the purpose of diagnosing and treating patients. (Ex. 30 at §§ 1.7, 2.1.) The 2003 License also contemplated a remedy for out-of-Field sales: It required Roche to disgorge its profits to IGEN by paying 65% of all revenues from undisputed out-of-Field sales. (Ex. 30 at § 2.5(b).) Both the in-Field sales and the out-of-Field sales (provided they were not deliberate) were within the purview of the 2003 License and Meso's consent.

The Court of Chancery already construed the scope of Meso's consent and held that Meso is not a party to the 2003 License, Meso cannot enforce that agreement's terms, and Meso cannot seek damages for sales governed by that contract. *See Meso*, 2014 WL 2919333 (Del Ch. June 25, 2014). Meso cannot now re-litigate the scope of that consent in another venue by recasting its claims as a patent case.[11] State contract law governs the allocation of patent rights. *See, e.g., T.B. Harms Co. v. Eliscu*, 339 F.2d 823, 826 (2d Cir. 1964). The already-decided state law issues are preclusive in this later patent case. *See Columbia Cas. Co. v. Playtex FP, Inc.*, 584 A.2d 1214, 1216 (Del. 1991) ("[W]here a question of fact essential to the judgment is litigated and determined by a valid and final judgment, the determination is conclusive between

[11] Meso recently filed suit in Delaware Chancery Court challenging the judgment, but under Delaware law the judgment continues to have preclusive effect. *E.g.*, *Playtex Family Prod., Inc. v. St. Paul Surplus Lines Ins. Co.*, 564 A.2d 681, 684 n.2 (Del. Super. Ct. 1989) ("judgments on appeal are final for res judicata purposes"); Del. Ch. Ct. R. 60(b) ("A motion under this [Rule] does not affect the finality of a judgment or suspend its operation."); *accord Peterson v. Chicago Pub. Sch.*, 248 F.3d 1159 (7th Cir. 2000) (unpublished) ("But preeempting a defense [like claim preclusion] to some other suit is not a proper use of Rule 60(b). It is the second court that addresses the preclusive effect of the initial judgment."); *In re Williams*, 298 F.3d 458, 462 (5th Cir. 2002) ("The fact that a judgment may be subject to a motion for relief under Fed. R. Civ. P. 60(b) does not affect the finality of the judgment."); 18A Charles A. Wright et al., Fed. Prac. & Proc. Juris. § 4432 (3d ed.) ("preclusion should not be suspended merely because [a Rule 60] motion is pending").

the same parties in a subsequent case on a different cause of action." (quoting *Tyndall v. Tyndall*, 238 A.2d 343, 346 (Del. 1968))); 28 U.S.C. § 1738 (full faith and credit statute); *Marrese v. Am. Acad. of Ortho. Surgeons*, 470 U.S. 373, 381 (1985) ("[T]his Court has held that the issue preclusive effect of a state court judgment barred a subsequent patent suit that could not have been brought in state court." (citing *Becher v. Contoure Labs., Inc.*, 279 U.S. 388 (1929))); *Enovsys LLC v. Nextel Commc'ns, Inc.*, 614 F.3d 1333, 1343 (Fed. Cir. 2010) (holding that a state judgment of dissolution finalizing a divorce had preclusive effect in a federal patent case).

Meso, though not a party to the 2003 License, "consent[ed] to" the 2003 License agreement and "consent[ed] to and join[ed] in the licenses granted" in the License agreement. (Ex. 30 at A-01153); *Meso*, 2014 WL 2919333, at *28. The 2003 License, to which Meso consented, covered both in-Field sales and the remedy for out-of-Field sales. (Ex. 30 at §§ 1.7, 2.5.) Meso admits that it was entitled to none of the payments that Roche would owe for undisputed out-of-Field revenues. *Meso*, 2014 WL 2919333, at *7, 21 n.162. As the Chancery Court observed, Wohlstadter acknowledged and complained about the scope of the 2003 License:

> Through the "out-of-field" sales provisions of the proposed new license between [BioVeris] and Roche, in effect, IGEN is granting ROCHE the ability to sell products outside of the IVD market so long as Roche does not "know" that the use of the products is outside of IVD. If Roche makes any out-of-field sale, Roche's only consequence is to pay 65% of undisputed revenues earned the prior year and only after Roche has been informed by IGEN of the out-of-field sales. The license does not terminate for out-of-field sales. Therefore, Roche can sell with impunity outside the field, with the only penalty being a small "toll," which broadens Roche's ability to directly compete with MSD.

*Id.* (citations omitted). (*See* Ex. 29)

Meso knew the scope of the licenses granted to Roche in the 2003 License and consented to them. *Id.*; (Ex. 30 at A-01153.) The scope of Meso's consent, both to the License agreement and to the licenses granted in the License agreement, is coterminous with every sale Roche could make under the 2003 License—both in-Field sales and "unknowing" out-of-Field sales. While Roche owed BioVeris a penalty payment for undisputed out-of-Field sales, the 2003 License permitted Roche to continue to make sales to customers it learned were using its products out of Field until BioVeris sent written notice requesting Roche to stop making those sales. (Ex. 30 at § 2.5.) Meso, having consented to the 2003 License, cannot challenge sales within its framework: (1) in-Field sales; (2) sales to customers whom Roche did not know would use its products out of Field; and (3) sales to customers whom Roche has learned use the products out of Field but for whom BioVeris has not sent written notice to Roche to stop such sales.

The Court of Chancery left open the possibility that Meso could recover damages in a patent case if Roche made "deliberate" out-of-Field sales because those sales could be beyond the scope of its consent, *Meso*, 2014 WL 2919333, at *28 (assuming, of course, that Meso can persuade a jury that it has the "broad" license rights that it seeks to enforce). That any claim to Meso is limited to "deliberate" out-of-Field sales, at most, is a matter of issue preclusion. In addressing this issue, the Vice Chancellor's decision relied in part on the July 2003 memo from Wohlstadter, which explained that the 2003 License permits Roche to sell in the Field and also to sell outside of the Field "so long as Roche does not 'know' that the use of the products is outside of IVD." *Meso*, 2014 WL 2919333 at *7 (Ex. 29 at A-01124). It follows, then, that—at a minimum—a "deliberate" sale is one where Roche knows that the customer is using the products for out-of-Field uses. (*Id.*; *see also* Ex. 30 at §§ 1.7(c), 2.5(c).) The 2003 License did not impose on Roche a duty to inquire as to customers' use. (Ex. 30 at §§ 1.7(c), 2.5(c).)

Roche produced a list of customers that may be considered "single use" out-of-Field customers under the 2003 License, and this motion does not concern the customers on that list. For dual-use customers, however, the implications of the Court of Chancery's decision are straightforward: Meso must present evidence, as to particular customers, that Roche knew, when it made sales to each customer, that the products would be used out-of-Field. Meso has proffered *no* such evidence for *any* dual-use customer. The fact that Roche no longer takes affirmative steps to warn against out-of-Field uses is insufficient to show that Roche *knowingly* made out-of-Field sales by selling to *potential* dual-use customers. Under the Vice Chancellor's decision, Meso is not a party to the 2003 License (and, hence, has no right to enforce its product-labeling requirements). *Meso*, 2014 WL 2919333, at *25, *28. Even under the 2003 License, Roche has no duty to inquire about its customers' use of products. (Ex. 30 at §§ 1.7(c), 2.5(c).)

This is not a typical patent infringement case because Roche not only has a license to use the patents but Meso consented to the 2003 License Agreement and the Chancery Court upheld that consent. Having completed discovery, Meso must demonstrate Roche made those sales of an accused product *deliberately* to be used out-of-Field.[12] Meso has proffered no such proof as to potential dual-use customers, and the Court should grant summary judgment as to all claims relating to sales of accused products to dual-use customers.

**B. Roche Is Not Liable for Indirect Infringement.**

**1. There Is No Evidence That Roche *Actively* Induced Infringement.**

[12] While direct patent infringement itself is a strict liability tort, *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 n.2 (Fed. Cir. 1996), Roche's liability here is premised on whether Roche went beyond the scope of Meso's consent to the 2003 License; under the Vice-Chancellor's decision, that limits potential infringement liability to deliberate out-of-Field sales.

Similarly, discovery has uncovered no evidence to support Meso's induced-infringement theory as to any dual-use customer. (*E.g.*, D.I. 42 at Am. Counterclaim ¶¶ 38, 50, 61, 74, 87, 100, 113, 124, 136, 145.) An inducement claim requires Meso to show both direct infringement and that Roche knowingly and *actively* induced infringement *with specific intent to encourage* its customers' infringement. *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005). But Meso cannot show that Roche "knowingly aided and abetted" dual-use customers to directly infringe the method patents via an "affirmative act" such as causing or urging its customers' infringement. *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630, 631 n.3 (Fed. Cir. 2015) (internal quotation marks omitted); *see also* 35 U.S.C. § 271(b) ("Whoever *actively* induces infringement of a patent shall be liable as an infringer") (emphasis added). The Court should grant summary judgment to Roche on inducement because Meso has not met, and cannot meet, its burden. Roche simply does not do anything that could be considered *active* inducement, as the statute requires.

Meso alleges that the method claims are implicated when an instrument operator, or "user," adds a sample to Roche's instruments and the instruments then performs the steps of the methods, which include mixing the sample with reagents and microparticles to form a composition for performing a binding assay, to which electricity is added to effect the ECL reaction. (D.I. 42 at Am. Counterclaim at ¶¶ 69-70, 82-83, 95-96, 108-09, 122-23.) Roche does not control the instruments that perform the methods, except in connection with installation, calibration, and maintenance, which are necessary predicates to licensed in-Field use. (Ex. 74 at ¶¶ 2-4.) Recognizing that the methods are performed only by customers, Meso alleges that "Roche Diagnostics encouraged and facilitated infringing uses of the Accused Products through the creation and dissemination of promotional and marketing materials, instructional materials,

product manuals, and/or technical materials to its customers." (D.I. 42 at Am. Counterclaim ¶¶ 38, 50, 61, 74, 87, 100, 113, 124, 136, 145.) Those allegations, even if they were true, do not amount to active inducement. The actual evidence cannot sustain Meso's claim.

The patented methods do not cover *only* in-Field or *only* out-of-Field uses. Rather, to the extent that a customer is performing the methods when conducting an assay, the customer is doing so whether it conducts the assay to diagnose and treat a patient or for some other purpose. (Ex. 74 at ¶¶ 5-6.) Meso does *not* allege that any of Roche's instructional or technical customer materials instruct customers *how to use products out-of-Field*. But that is what active inducement requires, particularly on the facts here. Even under Meso's unduly broad theory of infringement, Roche customers may use immunoassay products for testing related to patient medical decisions. (*E.g.*, D.I. 42 at Am. Counterclaim ¶ 20.) Therefore, any use of the method *in-Field* does not meet the direct infringement prerequisite to indirect infringement. Moreover, Roche can make an infinite number of instrument and reagent *sales* without ever infringing a method claim. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993) (sales of products that infringe method do not constitute infringement of the method). It is only when a customer's unlicensed use was actively encouraged and specifically orchestrated by Roche that liability for indirect infringement is in play. *See id.* This high hurdle is made even higher by Meso's consent to the 2003 License.

Roche's removal of product labeling about the Field restrictions simply does not cut it. (*See* Ex. 40.) Failure to instruct customers not to infringe is not active inducement under any view. That would "turn[] the legal test on its head." *See Takeda*, 785 F.3d at 632, n.4. Regardless of Roche's potential labeling obligations to BioVeris under the 2003 License, Roche is not obligated *by patent law* to take affirmative steps to ensure others avoid infringement. *See*

*id.* Rather, Roche must take care not to instruct customers specifically how to use the products in an infringing matter. Meso offers no evidence that Roche's marketing materials or labeling practices would necessarily lead any hospital or other lab performing diagnostic tests also to use the accused products out-of-Field.

Even knowledge of customer infringement is not enough to show inducement. Therefore, even if Meso could demonstrate an issue of fact on Roche's issue preclusion argument, *supra* Part I.A., it still falls short on inducement. "[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). In *Takeda*, the Federal Circuit held that knowledge of certain physicians' off-label use of a drug would not establish inducement. 785 F.3d at 631-32. With the possible exception of single-use out-of-Field customers, Meso cannot show that Roche even knows which of its potential dual-use customers use the products out-of-Field and to what extent. (Ex. 56 at 153:8-20, 242:16-243:6; Ex. 57 at 215:8-217:5.)

Nor do Roche's 2007 communications to the market generally that it had acquired BioVeris and believed (as it still believes) that it had rights to sell out-of-Field establish active inducement. (*See* Exs. 42, 43, 44.) These actions simply do not advertise any specific infringing use; nor do they instruct customers how to use products outside the Field with "specific intent to encourage infringement." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009). Moreover, the only evidence that Meso has so far pointed to—these 2007 communications with customers—took place nearly four years before the first sales precluded by the statute of limitations. If that is the only evidence Meso has after substantial discovery, a jury could not find for Meso on inducement.

This evidence is not enough, and Meso has no other evidence of active inducement. (*See, e.g.*, Ex. 65 at 39:4-41:8, 44:9-18.) Because no genuine dispute of material fact exists, the Court should grant summary judgment for Roche on inducement as to all dual-use customers.

**2. Meso's Contributory Infringement Claim Fails as a Matter of Law Because Roche's Products Have Permissible, Licensed Uses.**

Meso, likewise, cannot meet its burden to establish the elements of contributory infringement, namely: "1) that there is direct infringement, 2) that the accused infringer had knowledge of the patent, 3) *that the component has no substantial non-infringing uses*, and 4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (emphasis added). Under 35 U.S.C. § 271(c), contributory infringement is reserved for a context where a manufacturer sells a component part of a patented invention knowing that the component is especially made for use in such a patented invention, without authority to do so. *Id.* But even if the contributory infringement framework were applied here, its elements are not satisfied. Roche's products have a substantial non-infringing use. Specifically, Roche's accused products can be used within the 2003 License Field. (*E.g.*, D.I. 42 at Am. Answer ¶¶ 22-26.) Because a substantial non-infringing use exists, Meso's contributory infringement claim fails as a matter of law.

"[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. It is Meso's burden to prove the lack of a substantial non-infringing use here. *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012). While this test is more nuanced than a simple mathematical formula, *cf. id.*, the non-infringing use of Roche's products is substantial by any measure. Because Roche's sales within the defined Field are explicitly permitted by the 2003 License, Meso has not (and cannot) establish that a substantial non-infringing use does not exist.

No genuine dispute of material fact exists on contributory infringement, and summary judgment is, therefore, appropriate.

## II. ROCHE IS ENTITLED TO SUMMARY JUDGMENT OF NON-INFRINGEMENT FOR CLAIM 82 OF THE '939 PATENT AND CLAIMS 1, 26, 28, AND 29 OF THE '485 PATENT.

This Court has construed the patent claims and under this Court's construction, Meso's [redacted] (*See* Ex. 54, at Exs. C, J at A-01723-35; D.I. 114.) Meso's "kit" theory depends on ProCell—Roche's reagent that contains TPA for the ECL reaction—being "packaged" together with Roche's other immunoassay reagents.[13] But the undisputed facts show that ProCell ***is not*** included in any "kit" for Roche's reagent packs. This Court defined the term "kit" as used in the patents-in-suit as "a set of materials packaged to be used together[.]" (D.I. 114 at 6.) This definition, therefore, turns on the term "packaged." (*Id.*) All of the evidence shows that ProCell is packaged *separately* from Roche's reagent packs. (Ex. 56 at 174:20-175:8, 178:23-180:16; *see, e.g.*, Ex. 49 at A-01598 (Roche reagent pack for CEA listing ProCell as a material "not provided")). Indeed, not only are ProCell and Roche reagent packs packaged separately, but they are shipped separately due the products' varying temperature storage requirements. *Id.*

---

[13] All of Meso's Asserted Claims under the '485 Patent cover a "kit" that must include, among other things, "an amine or amine moiety" capable of acting as "a strong reducing agent." *See* Ex. 54 at Ex. C. [redacted] *Id.* at A-01669, A-01683. Meso's Asserted Claim 82 under the '939 Patent covers a "kit" that must include "at least one assay component selected from the group consisting of: (a) an electrochemiluminescence coreactant[.]" *See* Meso Final Infringement Contentions, Ex. J at A-01723. [redacted] *Id.* Ex. A-01729.

[redacted] (Ex. 73 at 240:12-247:14.) That position is inconsistent with both the Court's *Markman* construction of the term "kit" and the rationale given by the Court for that construction. (D.I. 114, at 5-6 ("Meso counters that the set of materials need only be used together and that nothing in the claims requires the materials also to be packaged together. . . . But the Court agrees with Roche that Meso's position renders the word "kit" meaningless, because the claims already specify that the materials must be used together.").) Something more than mere post-shipment "use together" is required under this Court's construction, lest the term "packaged" become superfluous. (*Id.*) Because the claim term "kit" requires that the reagent packs and ProCell be "packaged" together, no Roche product falls within the meaning of "kit" under the applicable patents.

When a claim for infringement relies on an interpretation that would vitiate the court's claim construction, the alleged infringer is entitled to summary judgment of non-infringement on that same claim. *Cooper Notification, Inc. v. Twitter, Inc.*, 867 F. Supp.2d 485, 495–96 (D. Del. May 25, 2012) (Stark, J.), *aff'd*, 545 F. App'x 959 (Fed. Cir. 2013) (granting summary judgment on non-infringement when facts demonstrated that defendant's accused system did not fit within the Court's construction of the claim). That is squarely the case here. Accordingly, Roche is entitled to summary judgment on non-infringement for Claim 82 of the '939 Patent and Claims 1, 26, 27, and 29 of the '485 Patent.

## III. ROCHE IS ENTITLED TO SUMMARY JUDGMENT OF NON-INFRINGEMENT FOR CLAIM 10 OF THE '607 PATENT FOR THE ACCUSED ASSAYS BECAUSE THE LINKER GROUP USED IN THOSE

**ASSAYS IS DIFFERENT FROM THE LINKER GROUP REQUIRED IN CLAIM 10.**

Roche is also entitled to judgment of non-infringement on Claim 10 of the '607 patent. Roche's tutorial provides background about the ECL reaction. The '607 patent relates the chemical structures that ultimately link the analyte of interest (or its analogue) with the ruthenium (which generates light when the analyte of interest is present in a patient sample). On the undisputed facts, Meso cannot establish infringement for several[14] of the accused assays under the '607 patent.

Claim 10 of the '607 patent requires that the linker between ruthenium and the analyte of interest be selected from one of five chemical compounds: (1) $–CH_2–(CH_2)n–CHO$; (2) $–CH_2–(CH_2)_n–COOH$; (3) $–CH_2$; (4) $(CH_2)_n–NH_2$; or (5) $–CH_2–(CH_2)_n–CO_2–NHS$. '607 Patent at 89:25-90:25. [redacted] (Ex. 63 at A-01972-92), [redacted] (Ex. 68 at A-02102, A-02109, A-02135.) [redacted]. But Meso is ultimately inviting the Court to rewrite the patent claim. This Court should decline that invitation. *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1373 (Fed. Cir. 2004) (affirming grant of summary judgment for non-infringement and refusing to rewrite the patent claim); *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("[C]ourts do not rework claims. They only interpret them.") (internal quotation marks omitted).

---

14 [redacted] (Ex. 63 at A-01971.) [redacted] *See* Ex. 54 at Ex. I, A-01704.

Under the Court's construction of the claims, Meso's infringement allegations must be dismissed.

[redacted] (01/29/19 White Rep. pp. 10-31.) [redacted] (03/20/19 Crooks Rep. pp. 37-44, 70.) [redacted] Therefore, because the accused assays lack the required linker of Claim 10 of the '607 Patent, Roche's assays do not infringe it.

Meso tries to escape this reality by suggesting that the patent means something other than what it says. [redacted] (Ex. 69 at A-02213 (emphasis added).) But that is not what the Claim says. The plain language of the Claim requires that the linker—not the precursor to the linker—be of the form –COOH. Even if one of skill in the art would recognize that carboxylic acid would be only a precursor rather than the linker, it is not the job of the Court to rewrite the claims to fix the alleged error. *Chef Am.*, 358 F.3d at 1373; *Intervet Am.*, 887 F.2d at 1053. Notably, Claim 6 of the '607 patent expressly recites a compound formed from the precursor: "A compound which is the product of a linkage reaction between X and Z …" (Ex. 24 at 87:65-68.) Thus, when the applicant wanted to claim a compound formed from a precursor, it knew how to do so. Claim 10, by contrast, claims the resulting compound: "A compound having the structure X—Y—Z. …" (*Id.* at 89:25-30.) Roche is entitled to summary judgment that its 10 accused assays do not infringe claim 10.

## IV. ROCHE'S PLATINUM, REUSABLE ELECTRODES DO NOT INFRINGE MESO'S LICENSE RIGHTS TO "DISPOSABLE ELECTRODES."

The Court should also dismiss all claims based on Meso's argument that the platinum electrodes in Roche instruments infringe Meso's alleged exclusive rights to use "disposable electrodes." Roche's platinum, reusable electrodes are not "disposable electrodes" within the meaning of the IGEN/Meso License and the JVA.[15] (Exs. 3, 4, 19.) In response to Roche's Phase I summary judgment motion concerning disposable electrodes, Meso argued that the issue was more properly presented as a Phase II infringement issue. (D.I. 109; 10/23/18 Tr.) The Court agreed with Meso's position. (D.I. 153 at 12-13.) Now that discovery is complete and the factual record developed, there is no legitimate factual dispute that Roche's electrodes—used, cleaned, and re-used about 50,000 or 100,000 times before replacement—are not "disposable" within the meaning of the JVA. (Ex. 75 at ¶ 3.) For many years before this litigation began, Meso was perfectly consistent about the meaning of "disposable electrodes," and its own definition excludes Roche's platinum, reusable electrodes. Therefore, summary judgment is appropriate.

Meso is judicially estopped from claiming that the Roche electrodes infringe Meso's license rights in light of Meso's representations to the federal court in Maryland distinguishing IGEN and Roche's electrodes from Meso's disposable electrodes.[16] (*See* Ex. 11 at A-00418

---

[15] The 1995 License Agreement used the term "modified electrodes," which was changed to "disposable electrodes" as part of the 2001 amendment. *Compare* Ex. 3 at § 1.4 and Ex. 19 at § 1, MESO00041186. Despite amending the word "modified" to "disposable," the parties did not change any of the types of examples listed in the second sentence of Section 1.11.

[16] Indeed, the district court relied on these representations to limit discovery that Roche wanted for its counterclaim. (*E.g.*, Ex. 23 at 16:5-17:6.) Having obtained the relief it sought in 2001, Meso cannot now claim that Roche's products, which have used the same ECL technology

("MSD's use of the multi-array technology has focused on the combined use of Igen's ECL technology with a multi-chambered plate and disposable electrodes. . . . In contrast, the ECL technology exploited by Igen and incorporated into the instruments developed by [Roche] under the license agreement measures . . . through a flow cell using a permanently installed electrode.").) [redacted] Based on Dr. Meyerhoff's conclusion, the court concluded that Meso need not comply fully with a subpoena issued by Roche. (Ex. 23 at A-00853-54.)

[redacted]

since the 1990s, incorporate disposable electrodes. *See generally Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. Gen. Motors Corp.*, 337 F.3d 314, 319-20 (3d Cir. 2003).

[17] [redacted] (Ex. 22 at A-00826.) [redacted] (Ex. 19 at ¶ 1(A).)

[redacted]

Further, in March 2001, Wohlstadter obtained U.S. Patent No. 6,207,369 B1 for his invention "relat[ing] to novel, disposable electrodes," distinct from "permanent flow cell electrode[s]," which require "washing and/or cleaning to eliminate carry-over and regenerate a uniform electrode surface . . . ." (Ex. 14, A-00528-29, Col 6-7.)[18] In September 2002, Meso filed U.S. Patent No. 7,858,321 B2, noting that the commercially available instrumentation used "flow cell-based designs with permanent reusable flow cells." (Ex. 45, Col. 1:59-65.) At that time, both IGEN and Roche offered instruments utilizing the same flow cell technology for commercial sale. [redacted]

By Meso's own admissions, Roche's platinum reusable electrodes simply are not "disposable" as that term was used by the parties in the IGEN and Meso License and the JVA.

[18] In a 2004 publication, Jacob Wohlstadter and James Wilbur (Meso's two 30(b)(6) designees in Phase 1) described Meso's launch of its products in 2001 as "the *first* commercial ECL instruments for measuring ECL from solid-phase assays carried out on disposable electrodes." (Ex. 32 at A-01231 (emphasis added); Ex. 51 at 135:6-137:16.)

*Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1160 (Del. 2010) (courts "will give effect to the plain-meaning of the contract's terms and provisions."). Therefore, the Court should grant summary judgment for Roche on Meso's claim that the platinum, reusable Roche electrodes infringe Meso's rights to the use of "disposable electrodes."

## V. MESO'S DAMAGE EXPERT, MR. QUENTIN MIMMS, DOES NOT PRESENT A RELIABLE METHODOLOGY UNDER *DAUBERT*.

The proposed expert opinions of Mr. Quentin Mimms, Meso's damages expert, should be excluded because they do not meet *Daubert*'s requirement that: (1) the opinion be reliable; and (2) the expert's opinion relate to the facts. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); Fed. R. Evid. 702. Here, "there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (1997). Meso cannot prove that it meets all of the standards for admissibility by a preponderance of evidence. *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999).

### A. Mr. Mimms' Damages Theory.

Mr. Mimms opined that a reasonable royalty on out-of-Field sales represents the appropriate method for measuring damages and that he needed to construct a hypothetical negotiation between a willing licensor and a willing licensee at the time of first infringement. (Ex. 62 at ¶¶ 8, 116.) But Mr. Mimms then applied an approach that does not match that methodology.

Ignoring the out-of-Field sales that occurred in 2003 or 2004, Mr. Mimms assumed that [redacted] (Ex. 62 at ¶¶ 50 n.97,

118, 127, 185; Ex. 70 at ¶¶ 8-10.) Stated slightly differently, Mr. Mimms concludes that Meso held all the intellectual property rights that stood between Roche and its ability to sell outside the Field specified in the 2003 License. [redacted] (Ex. 62 at ¶ 188.) [redacted] (*Id.*)

Mr. Mimms' assumption that [redacted] was critical to his analysis. (Ex. 62 at ¶¶ 77, 118; Ex. 70 at ¶¶ 8-12.) If, by contrast, Roche and Meso had negotiated the hypothetical license prior to Roche acquiring BioVeris in late June 2007, that license would not grant freedom to operate because BioVeris could still enforce the 2003 License Agreement to require the 65% payment and to prevent further out-of-Field sales by Roche. By putting his hypothetical negotiation only after the BioVeris acquisition, Mr. Mimms artificially created the "last hurdle" to FTO and the accompanying leverage.

Mr. Mimms [redacted] (Ex. 70 at ¶¶ 4, 48-52.) [redacted]

(Ex. 62 at ¶¶ 8, 94; Ex. 70 at ¶¶ 48-52)[19] [redacted] (Ex. 62 at ¶¶ 48-52.)

Mr. Mimms did not attempt to apportion the value of the FTO between the 10 patents raised in the counterclaim and the remainder of the 100+ patent portfolio owned by BioVeris. He also gave no credit for the value of other inventions, innovations and patents contributed to Roche's immunoassay products, made no allocation for the relative portions of value Roche anticipated outside the U.S., and made no apportionment among the patents alleged here and the rest of the BioVeris patent portfolio. (Ex. 62 at ¶¶ 55–69; Ex. 70 at ¶¶ 48-52.) Instead, he gave credit for his entire freedom to operate valuation to the ten patents Meso relies upon in its counterclaim. Because Mr. Mimms' methodology is fundamentally flawed, his opinion is unreliable under *Daubert*.

**B. Mr. Mimms' Opinions Are Unreliable Because He Derives His Reasonable Royalty Rate for the 10 Patents-in-Suit from** [redacted]

Mr. Mimms' opinions on the royalty rate are unreliable because [redacted]

19 [redacted]

[redacted] Because Mr. Mimms did not discount his royalty rate to account for the patent and contractual limits beyond those at issue in this action, his analysis is flawed.

**1. Mr. Mimms Did Not Discount His Royalty Rate To Account for the 100+ Patents in BioVeris' Portfolio That Are Not Asserted in This Action.**

One flaw in Mr. Mimms' analysis is that [redacted] (Ex. 72 at 137:11-141:11; Ex. 70 at ¶¶ 4, 48-52.) [redacted] (Ex. 70 at ¶ 4.) [redacted] (*E.g.*, Ex. 72 at 137:11-141:11.) [redacted] (and Dr. Wilbur, *see infra* Ex. 73 at 49:23-61:17) [redacted]

Mr. Mimms also fails to account for the fact that Roche paid hundreds of millions of dollars to acquire BioVeris. [redacted] (Ex. 72 at 157:7-159:17, 161:16-162:1.) [redacted] (Ex.

66 at 168:13-170:21.) Accordingly, Mr. Mimms' methodology is unreliable, and should be excluded.

The Federal Circuit and district courts have consistently held that it is not appropriate to derive a reasonable royalty based on other licenses that include rights broader than the patents-in-suit without discounting the licensing fee to account for amounts paid for the other rights. *See Bandag, Inc. v. Gerrard Tire Co., Inc.*, 704 F. 2d 1578, 1582 (Fed. Cir. 1983) ("[A] fee to be used in measuring damages to be paid for infringement of one patent cannot also encompass payments for permission to practice other patented inventions."); *Trell v. Marlee Elec.Corp.*, 912 F.2d 1443, 1447 (Fed. Cir. 1990) ("Marlee's infringement related to only one aspect of Trell's invention, as compared with the scope of the Bewator license. The district court's apparent failure to consider the fact that the Bewator license was exclusive and that it encompassed the right to other inventions compels reversal."). In both *Bandag* and *Trell*, the Federal Circuit *reversed* the damages awards because those awards were based on other licenses that encompassed rights broader than the patents-in-suit. *Id.*

Courts have excluded expert testimony on this basis. *See, e.g., Lighting Ballast Control, LLC v. Philips Elecs. N. Am. Corp.*, No. 09-00029, 2011 WL 7575006 at *4 (N.D. Tex. June 10, 2011); *Golden Bridge Tech. v. Apple Inc.*, No. 12-04882, 2014 WL 4057187, at *2 (N.D. Cal. June 1, 2014); *see also AVM Techs., LLC v. Intel Corp.*, No. 10-00610, 2013 WL 12633, at *3-4 (D. Del. Jan. 4, 2013) (deferring decision to exclude the expert until before the beginning of trial). In *Lighting Ballast*, the court excluded the expert's testimony regarding a particular license with GE for two patents, where only one of the patents was asserted against Philips in that case. *Lighting Ballast*, 2011 WL 7575006 at *4. The court found that the expert's opinions

were unreliable because he did not discount the royalty rate to account for the patent that was not asserted against Philips (the '106 patent):

> While Gallagher contends that he properly considered, and discounted, the value of the '106 patent to the GE License, the record belies his assertion. Gallagher simply stated that it was his "understanding" that the '106 patent was immaterial to the consummation of the GE License, without any explanation whatsoever of where that understanding came from or what it was based upon. Such an "understanding" does not constitute a reliable or helpful expert analysis of the GE License.

*Id.*

In both *Golden Bridge* and *AVM*, the courts found the expert opinions unreliable because they relied on licenses for entire patent portfolios as comparable licenses. *Golden Bridge*, 2014 WL 4057187, at *2; *AVM*, 2013 WL 126233, at *3. The expert in *Golden Bridge* allocated the entire value of Apple's portfolio licenses with Ericsson and Nokia to a tiny subset of the patents and standards in the portfolios, which the court found to be an "implausible assumption." 2014 WL 4057187, at *1-2. The court excluded his testimony, reasoning that "[u]nder established Federal Circuit law, an expert may not rely on broad licenses that cover technologies far beyond the patents-in-suit without accounting for the differences in his calculations." *Id.* at *2.

Similarly, the expert in *AVM* relied on a license that included dozens of patents to arrive at his opinion regarding a reasonable royalty rate for a single patent. *AVM*, 2013 WL 12633, at *3. The court reasoned that "a patentee may not argue that prior licenses granting rights to entire portfolios of patents are comparable to a license that the parties would have negotiated for a single asserted patent" and "[n]o reasonable juror could consider these broad portfolio license agreements to be comparable in scope to a license for only the '547 patent." *Id.*

Mr. Mimms' analysis suffers from the same flaw as the expert opinions excluded in these cases. Neither Mr. Mimms nor Dr. Wilbur contend that the other 100+ patents are valueless. To

the contrary, [redacted] (Ex. 72 at 139:2-140:9; Ex. 73 at 51:20-52:22, 54:20-56:3.) Yet, Mr. Mimms extrapolates his reasonable royalty assessment of the 10 patents-in-suit from [redacted] but without apportioning the value of the 10 asserted patents. (Ex. 62 at ¶ 187; Ex. 59 at 305:20-306:4; *see also* Ex. 41.) Mr. Mimms analysis could only be tenable if the other 100+ patents that are not at issue in this action are completely valueless.

Mr. Mimms' own analysis, therefore, is internally inconsistent. [redacted] (Ex. 62 at ¶ 187-88; Ex. 70 ¶¶ 4, 48-52.) [redacted] (Ex. 62 at ¶¶ 161, 180, 184-90; Ex. 70 at ¶¶ 51, 53, 67.) [redacted] (Ex. 73 at 54:20-56:3; 78:14-80:18, 83:14-25; *see also* Ex. 66 at 168:13-170:21.) The troubling consequence is that, if Mr. Mimms' analysis were accepted, Meso *might sue Roche yet again* under some of these "core" patents after this case is finished, even though the entire worldwide value of BioVeris's entire patent portfolio—plus the value of the reallocation of the 2003 License (discussed *infra*) and the other aspects of BioVeris's business—has already been allocated to the 10 patents in suit.

Because Mr. Mimms improperly conflates the value of the 10 asserted patents with [redacted], his opinion should be excluded.

**2. Mr. Mimms Did Not Discount His Royalty Rate To Account for the Contractual Obligations Roche Re-allocated by Acquiring BioVeris.**

Not only did Mr. Mimms fail to discount his royalty rate to account for the 100+ BioVeris patents that are not asserted in this action, he also failed to discount his royalty for the 2003 License terms that allowed the then independent BioVeris to receive a 65% payment on out-of-Field sales and that gave BioVeris the option of allowing or stopping Roche out-of-Field sales. Those contractual obligations would exist and limit Roche's freedom to operate even if Roche had obtained the hypothetical license from Meso as early as 2003 or 2004.

The 2003 License not only defined the Field but also included a provision for a 65% payment by Roche for any revenues realized from out-of-Field sales. (Ex. 30 at §§ 1.7, 2.1, 2.5) IGEN sought that rate to eliminate Roche's profits on such sales and to eliminate the incentive for Roche to sell out of Field. (Ex. 48 at 1052.) The 2003 License also provided that the Field restrictions (and 65% payments) continued for the life of the License. (Ex. 30 at § 1.15.) Roche was obligated to pay BioVeris 65% on all out-of-field sales, *worldwide*, until at least the expiration of the last-to-expire of "the ECL Patent Rights" (such rights including a 27-page list of patents and applications). (Ex. 30 at §§ 1.15, 2.1; *id.*, Ex. A.)

By acquiring BioVeris in 2007, Roche's obligation to pay BioVeris 65% for all out-of-field sales, ***worldwide*** until the last patent anywhere expired, became an obligation that it owed to its own affiliate. (Ex. 30 at § 2.5(b); Ex. 62 ¶ 51; *id.* ¶ 71.) Accordingly, the BioVeris acquisition (and the valuations leading up to it) was not commensurate with the rights asserted in this action, which involves only 10 patents. *See Bandag*, 704 F.2d at 1582 ("[I]t must also be

acknowledged that a particular fee is not the correct measure of damages unless that which is provided by the patentee to its licensees for that fee is commensurate with that which the defendant has appropriated.").

Mr. Mimms' failure to properly account for relief from the 65% payment obligations is significant. For example, even though many of the European patents expired in 2012, Roche would be obligated to pay 65% on all out-of-field sales in Europe beyond 2012 because other patents in non-European countries expired later (such as the Patents-in-Suit). (Ex. 30 at § 1.15(b), Ex. A; Ex. 62 at ¶ 161 (noting that the European patents expired in 2012); *id.* ¶ 145 (noting that the last Patent-in-Suit expires in 2021).) Therefore, Roche was obligated under the 2003 License to pay 65% on out-of-field sales in Europe at least through 2021, just as it was obligated to do so for out-of-field sales in the United States. (Ex. 30 at § 1.15(b); *id.* Ex. A.) The fact that some of the European patents may have expired in 2012 was irrelevant to Roche's payment obligations in Europe. (*Id.*) This is not because Roche's U.S. patents were so valuable, but because the 2003 License lasted until the last-to-expire patent, no matter in what country it was issued, expired. (*Id.* § 1.15.)

To take it a step further, the 2003 License covered later granted ECL patents owned by or licensed to BioVeris that "claim their earliest priority from a patent application filed by IGEN or an IGEN Affiliate on or before the Effective Time." (*Id.* §§ 1.5(b), 1.8.) This category includes, for example, European patent {EP 1 409 459 B1} (Ex. 26), *see, e.g.*, Ex. 30 at A-01162, which has been validated in 14 European countries. This patent, alone, would require Roche to pay BioVeris 65% on all out-of-Field sales, worldwide, *including in the United States*, until the EP patent has expired *on June 21, 2022*. So, even though the patents in suit will have expired long

before then, and even if all other U.S. patents have expired by then, Roche's obligation under the 2003 License would remain for all of its worldwide sales.

[redacted]

(Ex. 62 at ¶ 161 (emphasis added).) [redacted] (Ex. 66 at 169:20-170:21.) Mr. Mimms ignored these considerations.

Because Mr. Mimms did not understand the scope of the 65% payment obligations and contractual out-of-Field restrictions Roche was seeking to avoid by acquiring BioVeris (and because he accordingly did not account for the magnitude of those obligations in his royalty rate assessment), his damage estimates are unreliable and should be excluded.

### C. The Court Should Exclude Mr. Mimms' Testimony Because He Used an Incorrect Hypothetical Negotiation Date.

In addition to failing to discount the BioVeris valuations, Mr. Mimms used the wrong hypothetical negotiation date. In doing so, he improperly relies, almost exclusively, [redacted] – years after the date Roche began making the allegedly infringing sales. Therefore, his use of the wrong hypothetical negotiation date renders his opinions overinflated and unreliable.

**1. The Hypothetical Negotiation Date is the Date Just Before Infringement Began.**

Under Federal Circuit precedent, the hypothetical negotiation date is just before the date of first infringement because "[t]he key element in setting a reasonable royalty ... is the necessity for return to the date when the infringement began." *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 870 (Fed. Cir. 1993) (internal quotation marks omitted) (reversing the damages award because the district court used the wrong date). "[T]he correct determination of the hypothetical negotiation date is ***essential*** for properly assessing damages." *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 75 (Fed. Cir. 2012) (internal quotation marks omitted) (emphasis added).

The hypothetical negotiation date is "*just before infringement began*" in order to "ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement" on the eve of infringement. *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1376 (Fed. Cir. 2017) (internal quotation marks omitted) (emphasis added).[20] This date is essential because "[t]he value of a hypothetical license negotiated in [a given year] could be drastically different from one undertaken [the very next year]. . . . Indeed, factoring in the rapid development of biotechnical arts, a year can make a great difference in economic risks and

[20] *See also Acceleration Bay LLC v. Activision Blizzard, Inc.*, 324 F. Supp.3d 470, 488-89 (D. Del. Aug. 28, 2018).

rewards." *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 870 (Fed. Cir. 2003), *vacated on other grounds*, 545 U.S. 193 (2005).

Given the importance of using the correct hypothetical negotiation date, it is appropriate to exclude expert testimony that relies on the wrong date. *See, e.g.*, *Bos. Sci. Corp. v. Cordis Corp.*, 777 F. Supp. 2d 783, 795 (D. Del. 2011); *LaserDynamics*, 694 F.3d at 76 (remanding for a new trial because district court used the wrong date); *Wang*, 993 F.2d at 869–70 (remanding for a new damages determination because district court used wrong date). It is no answer for Mr. Mimms to say [redacted] (Ex. 72 at 100:17-102:13.) To the contrary, his freedom-to-operate approach—which he times to a period when Meso would stand as the last hurdle to freedom to operate—makes his timing selection critical to his analysis.

The book of wisdom is not a panacea for selecting an incorrect hypothetical negotiation date; if it were, then there would be no reason to select a date in the first instance. An expert could simply, as Mr. Mimms has done, select what he views as the most favorable facts (even though Mr. Mimms misunderstands those facts on which he is relying) and pick a nearby date. That is backwards. The hypothetical negotiation date comes first; the book of wisdom second.

**2. The Proper Hypothetical Negotiation Date is in 2003 or 2004 When the Allegedly Unauthorized Sales Began.**

It is undisputed that Roche made allegedly unauthorized sales years before [redacted] (Ex. 72 at 27:23–34:18.) For example, the sales data shows that [redacted]. (Ex. 36) Indeed, even prior to signing the consent to the 2003 License, Jacob Wohlstadter complained that the license would allow Roche to "sell with impunity outside the field with the only penalty being a small 'toll' . . .." *Meso*, 2014 WL

2919333, at *7. (Ex. 29 at A-01124.) More recently, Mr. Wohlstadter surmised that Roche was making unauthorized sales throughout the entire time period from late 2003 through 2006. (Ex. 65 at 38:14-21. ([redacted]).)

[redacted] (Ex. 70 at ¶ 7.) Mr. Mimms' selection of a hypothetical negotiation date years after the date when the allegedly unauthorized sales began is contrary to Federal Circuit precedent. *E.g.*, *LaserDynamics*, 694 F.3d at 76.

**3. Mr. Mimms' Use of the Incorrect Hypothetical Date Renders His Opinions Unreliable.**

Mr. Mimms' use of the wrong hypothetical negotiation date renders his opinions unreliable. Using a date years-too-late is improper because it does not allow an examination of the proper hypothetical negotiation construct, *i.e.*, the hypothetical negotiation the parties would have conducted to avoid prospective infringement. *See Id.* at 76. As the Federal Circuit observed: "Were we to permit a later notice date to serve as the hypothetical negotiation date, the damages analysis would be skewed because, as a legal construct, we seek to pin down how the prospective infringement might have been avoided via an out-of-court business solution." *Id.*; *see also Integra*, 331 F.3d at 870, *vacated on other grounds*, 545 U.S. 193 (2005) ("[A] hypothetical license negotiated in [a given year] could be drastically different from one undertaken [the very next year]. . . .").

For all of the above reasons, the Court should exclude the testimony of Mr. Mimms' because his use of the wrong hypothetical negotiation date renders his opinions unreliable.

## VI. DR. JAMES WILBUR'S OPINIONS SHOULD BE EXCLUDED UNDER *DAUBERT* AND FED. R. EVID. 702.

Meso intends to use its employee Dr. James Wilbur as a non-retained "hybrid" expert under Federal Rule of Civil Procedure 26(a)(2)(C) for opinions spanning numerous topics, including patent infringement. (Exs. 52, 64, 71.) Notably, Dr. Wilbur's anticipated testimony provides the foundation for several of Mr. Mimms' damages opinions. For instance, Mr. Mimms' damages calculations rely on Dr. Wilbur's delineation and application of "core" and "non-core" patents, as evidenced by Dr. Wilbur's most recent Rule 26(a)(2)(C) disclosure (which parrots the language included in Mr. Mimms' report). (Ex. 71 at A-02281-82; Ex. 62 at ¶ 94; Ex. 70 at ¶ 52.) Mr. Mimms similarly relies on Dr. Wilbur's representations on the difficulties Roche would have designing around certain patents. (Ex. 62 at ¶ 196.)

For the reasons below, certain of Dr. Wilbur's employee expert opinions fail to pass muster under Rule 702 and *Daubert*.

### A. Dr. Wilbur's Conclusory "Core Patent" Opinions are Inadmissible.

Meso intends to offer Dr. Wilbur's opinions as to which of the patents in suit are "core" patents and which are "non-core." (Ex. 71 at A-02281-82.) In his deposition, however, Dr. Wilbur testified that [redacted] (*See* Ex. 73 at 73:11-12.) [redacted] (*Id.* at 72:2-6 ([redacted]); *see also id.* at 70:14-74:21.) Moreover, Dr. Wilbur

appears to offer a broad interpretation that all the accused Roche products are covered by the core patents without any disclosure of the specifics for his analysis. [redacted]

(*Id*. at 82:11-25).

Conclusory legal opinions on infringement-related issues are inadmissible. *See MKS Instruments, Inc. v. Advanced Energy Industries, Inc*., 325 F. Supp. 2d 471, 473 (D. Del. 2004) (rejecting conclusory statements); *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, No. CV 07-127-LPS-MPT, 2014 WL 529983, at *4 (D. Del. Feb. 7, 2014) ("[A] court may exclude an expert's testimony or opinion if it is conclusory, lacks analysis, or the chasm between the analysis and opinion cannot be bridged.").

Moreover, Dr. Wilbur's opinions about "core" and "non-core" patents, w[redacted] were developed in the context of litigation, and *not* in the normal course of Dr. Wilbur's job responsibilities. (*See* Ex. 73 at 70:14-74:21.) Dr. Wilbur cannot offer such opinions, however, because hybrid employee-experts like Dr. Wilbur are limited to testifying from "personal knowledge they gained on the job." *Indianapolis Airport Auth. v. Travelers Prop. Cas. Co. of Am.*, 849 F.3d 355, 371 (7th Cir. 2017); *see also Downey v. Bob's Disc. Furniture Holdings, Inc.*, 633 F.3d 1, 6 (1st Cir. 2011) (holding that Rule 26(a)(2)(C) witness' testimony in case arose "not from his enlistment as an

expert but, rather, from his ground-level involvement in the events giving rise to the litigation."); *Avnet v. Motio*, 2016 WL 927194 (N.D. Ill. Mar. 4, 2016) (excluding CEO's testimony on infringement, validity, and damages because there was "nothing to indicate that [the witness] derived his opinions for any purpose other than this lawsuit…" reasoning that key determination was "whether he developed the disclosed opinions in the ordinary course of his work…or instead for this litigation"); *Meredith v. Int'l Marine Underwriters*, 2011 WL 1466436, at *4 (D. Md. Apr. 18, 2011) ("To the extent that a witness' opinion is based on facts learned or observations made 'in the normal course of duty,' the witness is a hybrid and need not submit a report. The same witness, however, must submit a report regarding any opinions formed specifically in anticipation of the litigation, or otherwise outside the normal course of a duty.").

For these reasons, any opinions by Dr. Wilbur about core and non-core patents or about what products and claims fall within a core or non-core category should be excluded.

**B. Dr. Wilbur's Infringement Opinions Are Likewise Conclusory and Were Formed for the Litigation and Should Therefore be Excluded.**

Meso also intends to offer Dr. Wilbur to testify that Roche's products infringe several of the patents at issue. [redacted] (Ex. 73 at 231:7-10.) [redacted] (*Id.* at 313:3-314:22, 316:6-317:3.) [redacted] (*Id.* at 316:19-21.) [redacted] (Wilbur 2019 Dep. at 228:3-229:17.)

Infringement opinions are inadmissible when offered by a purported expert who provides no analysis underlying the opinion. "[I]t is well settled that an expert's unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact." *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000). *See also XpertUniverse, Inc. v. Cisco Sys., Inc.*, No. CIV.A. 09-157-RGA, 2013 WL 865974, at *3 (D. Del. Mar. 7, 2013) (excluding expert's conclusion on direct infringement where opinions were conclusory and "the sort of *ipse dixit* that is not reliable because it is not the product of…scientific…expertise, or [ ] direct knowledge"). In *Magnetar*, the court excluded the infringement opinion of a technical expert who "fail[ed] to provide any analysis of how infringement was determined," and whose report "merely contained conclusory statements." *Magnetar* at *6. In excluding the expert's opinion, the court held:

> Hanlon's opinion lacks the proper grounds for his conclusions, because it is void of the necessary analysis for comparing each element of the claim to the accused product…. [T]he patentee's expert must set forth the factual foundation for his infringement opinion in sufficient detail for the court to be certain that features of the accused product would support a finding of infringement under the claim construction adopted by the court.

*Id.*

[redacted] (*Id.* at 316:6-317:3.)

[redacted] (*Id.* at 320:11-321:17.)

Dr. Wilbur's infringement opinions are thus inadmissible. Although hybrid witnesses (like Dr. Wilbur purports to be) need only provide disclosures and not reports, they are limited to testifying to their personal knowledge obtained through the normal course of their employment.

*Indianapolis Airport*, 849 F.3d at 371; *Downey*, 633 F.3d at 6; *Meredith*, 2011 WL 1466436, at *4. Here, [redacted]

Dr. Wilbur should be barred from offering infringement opinions as to any patents beyond those listed in his disclosure. [redacted] (Ex. 73 at 226:18-23; *see also id.* at 226:8-227:20.) As Dr. Wilbur's deposition testimony makes clear, Dr. Wilbur failed to perform a meaningful infringement analysis as to any of the patents in suit. It would be doubly wrong to permit Dr. Wilbur to surprise Roche with additional conclusory infringement opinions at trial.

### C. Dr. Wilbur's Opinion Construing the Patent Term "Kit" Contradicts the Court's Claim Construction Ruling.

Meso intends to offer Dr. Wilbur to testify to Meso's preferred construction of the term "kit" in Claim 1 of the '485 Patent. The Court already construed that term during the *Markman* phase of this case. Dr. Wilbur's construction of "kit" is inconsistent with the Court's claim construction order, and for that reason his testimony is inadmissible.

Opinions that are inconsistent with a court's claim construction are excludable. *See Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, 232 F. Supp. 3d 632 (D. Del. 2017) (holding expert's testimony was inadmissible where opinion was inconsistent with court's claim construction); *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, No. CV 15-152-RGA, 2018 WL 4691047, at *3 (D. Del. Sept. 28, 2018) (same).

Here, Dr. Wilbur asserts that Roche's ECL reagent rack packs are "kits" under the same construction that was rejected by this Court at the *Markman* hearing. (*See* D.I. 114 (rejecting Meso's construction that "kit" means "a set of materials for use together" and construing "kit" as meaning "a set of materials packaged to be used together").) [redacted] (Ex. 73 at 239:9-13), [redacted] (Ex. 73 at 241:6-16.) Meso cannot employ Dr. Wilbur's purported expert testimony to take another crack at claim terms already construed by the Court. Dr. Wilbur's "kit" opinion should be excluded.

### D. Dr. Wilbur Lacks Expertise and a Sufficient Basis on Which to Testify About Roche's Ability to Design around the Patents in Suit.

Meso intends to offer Dr. Wilbur's opinions regarding Roche's ability, and its costs, to design around the '607 Patent, the '939 Patent, and "core patents" in the BioVeris patent portfolio. (Ex. 64 at A-02028, A-02031; Ex. 71 at A-02281.) [redacted] (Ex. 73 at 114:22-116:20, 294:14-295:22.) Dr. Wilbur's generalized "work around" opinions are inadmissible because he failed to conduct any claim- and technology-specific analysis of potential alternative approaches to ECL, and he lacks relevant knowledge of Roche's products and business.

[redacted] (Wilbur 2019 Dep. at 85:5-11, 86:2-5 ([redacted]); *see also id.* at 84:14-86:16.) To the extent that Meso wanted to use an expert to look at the actual Roche information, Meso should have used an outside expert.

Moreover, Dr. Wilbur's opinions lack necessary foundation in that he [redacted] (*See* Ex. 55 at 123:4-123:7 ("[redacted]"); Ex. 73 at 309:14-310:1 ([redacted]).)[21] [redacted] (Ex. 73 at 127:2-13.)

[21] [redacted] (Ex. 73 at 24:24-26:17.)

Dr. Wilbur further lacks the expertise required to opine on Roche's assay development, as Dr. Wilbur does not have experience in Roche's market, the IVD market. [redacted] (*Id.* at 22:13-24:19.) [redacted] (*Id.* at 123:2-126:1.) [redacted] (*See id.* at 88:9-20.) [redacted] (*Id.* at 319:2-320:2.) Without relevant regulatory experience, Dr. Wilbur is not qualified to provide expert opinions about the steps and costs needed for Roche to design or redesign and commercialize its FDA-approved immunoassay products.

Because Dr. Wilbur lacks the analysis and foundation necessary to opine on Roche's resources and ability to design around patents, his opinions on these issues are inadmissible under Rule 702 and *Daubert*.

## CONCLUSION

This Court should grant judgment for Roche: (1) dismissing Meso's claims based on Roche's non-deliberate sales to "dual-use" customers; (2) dismissing Meso's indirect infringement claims as to dual-use customers; (3) holding that Roche's reagent packs are not "kits" under Claim 82 of the '939 Patent and Claims 1, 26, 28, and 29 of the '485 Patent; (4) holding that Roche's reagent packs do not infringe claim 10 in the '607 Patent; and (5) holding

that Roche's instruments do not infringe license rights that Meso has to the use of "disposable electrodes."

This Court should also exclude certain portions of the opinions of Meso's proposed experts Quentin Mimms and James Wilbur.

*/s/ Joel Friedlander*

Joel Friedlander (Del. Bar No. 3163)
Christopher Foulds (Del. Bar No. 5169)
FRIEDLANDER & GORRIS P.A.
1201 N. Market Street, Suite 2200
Wilmington, DE 19801
(302) 573-3500
jfriedlander@friedlandergorris.com
cfoulds@friedlandergorris.com

*Attorneys for Roche Diagnostics Corporation and BioVeris Corporation*

OF COUNSEL:

James T. McKeown (admitted PHV)
Jeffrey N. Costakos (admitted PHV)
Eric L. Maassen (admitted PHV)
Kimberly K. Dodd (admitted PHV)
Rachel M. Blise (admitted PHV)
Philip C. Babler (admitted PHV)
FOLEY & LARDNER LLP
777 East Wisconsin Avenue
Milwaukee, WI 53202
(414) 271-2400

Dated: May 15, 2019